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IN THE

Supreme Court of the United States

OCTOBER TERM, 1992

WILLIAM DAUBERT and JOYCE DAUBERT, Individually and as Guardians Ad Litem for JASON DAUBERT, and ANITA DE YOUNG, Individually and as Guardian Ad Litem for ERIC SCHULLER,
Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

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BRIEF OF PRODUCT LIABILITY ADVISORY COUNCIL, INC., NATIONAL ASSOCIATION OF MANUFACTURERS, BUSINESS ROUNDTABLE, AND CHEMICAL MANUFACTURERS ASSOCIATION AS *AMICI CURIAE* IN SUPPORT OF RESPONDENT

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QUESTION PRESENTED

Whether the Federal Rules of Evidence exclude from evidence scientific expert testimony which is not based on accepted scientific methods.

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INTEREST OF *AMICI CURIAE*

The Product Liability Advisory Council, Inc. is an association of industrial companies formed for the purpose of submitting *amicus curiae* briefs in appellate cases involving significant issues affecting the law of product liability. Its members include about 100 major manufacturers.

The National Association of Manufacturers of the United States of America is a non-profit voluntary business association representing more than 12,000 companies throughout the United States. NAM is affiliated with an additional 128,000 businesses through the National Industrial Council and the NAM Associations Council. NAM members are parties in cases nationwide and are interested in the fair administration of justice, which includes the appropriate use of scientific testimony.

The Business Roundtable is an association of the chief executive officers of approximately 200 of the largest companies in the nation. The Roundtable examines public issues that affect the economy and develops positions that seek to reflect sound economic and social policies.

The Chemical Manufacturers Association is a non-profit trade association whose member companies produce, market, and use industrial chemicals. Its members comprise more than 90 percent of the productive capacity for basic industrial chemicals in the United States.

This case is of paramount interest to *amici* because it illustrates the acute dangers to businesses and to society posed by the unchecked use of aberrant scientific testimony in the courtroom. While the district and appellate courts below acted properly in this case to filter out such testimony, other courts have not been so vigilant. The predictable result has been that businesses like respondent have abandoned the development of promising innovations and groundbreaking products because of the fear of unsound science in the courtroom and the enormous litigation risks this scenario presents. As principal voices of the business and manufacturing communities, *amici* are well suited to emphasize for the Court the impact of aberrant expert testimony on private litigants, and the need for courts to exercise responsible control over what is allowed to pass before juries in the guise of "expert" testimony.*

* Pursuant to Rule 37, letters of consent have been filed with the Clerk of the Court.

INTRODUCTION AND SUMMARY OF ARGUMENT

Judge Learned Hand once made an observation that goes to the heart of this case:

> No one will deny that the law should in some way effectively use expert knowledge wherever it will aid in settling disputes. The only question is as to how it can do so best.[1]

Amici submit that the Federal Rules of Evidence exclude expert scientific testimony when it has been developed without regard for accepted scientific methods. That is the precise situation in this case.

This case focuses on expert scientific evidence. Such evidence plays a vital and often dispositive role in modern litigation. For scientific evidence to be helpful to the factfinder it must meet some minimal threshold of reliability. To hold otherwise would be to allow a system of adjudication based more on chance than on reason.

An essential element of our system of dispute resolution is the principle that judgments reached in accordance with reliable evidence will promote accuracy and avoid mere speculation. The putative expert who offers to testify about issues of science without regard to the scientific method imperils the very foundation of rational decision-making. It is neither practical nor sufficient to rely on the give-and-take of cross examination to correct for expert scientific evidence offered without sound foundation. Indeed, admitting the testimony of experts whose methodology falls well outside the scientific mainstream undermines faith in our system of justice, deters investment in new technologies, and results in unwarranted judgments. This proceeding presents a chief case in point: respondent ceased distributing domestically the drug Bendectin in order to curb litigation expenses asso-

[1] Learned Hand, *Historical and Practical Considerations Regarding Expert Testimony*, 15 Harv. L. Rev. 40, 40 (1902).

ciated with that product, even though study upon study has now concluded that the attack on Bendectin was scientifically unfounded.

Amici believe that a rational system of dispute resolution requires that federal courts exercise their express authority under the Federal Rules of Evidence to scrutinize and monitor the quality of expert testimony, especially where, as here, that testimony is at odds with a rich and voluminous body of scientific literature. *Amici* support fully the development of innovative science, and believe that the Rules must be construed so as to impose standards for expert testimony which are not so high as to stifle this development, but not so low as to permit the introduction of aberrant science in the courtroom. The federal courts should use reliable science to help resolve legal disputes; they should not be asked to rewrite science.

In keeping with this Court's rules on *amicus* practice, this brief will not address issues that have been or are likely to be raised by the briefs of the parties or other *amici*, but will focus instead on four matters pertinent to this case but not likely to be fully addressed elsewhere. Part I demonstrates that experts have historically been afforded uncommonly wide testimonial latitude, and that this latitude has historically and necessarily been circumscribed by a series of "gateways," reaffirmed by the Federal Rules of Evidence, which protect the judicial process and ensure rational decision-making. Part II refutes petitioners' suggestion that the "adversarial system"—and, in particular, the availability of cross-examination—is an adequate check on unsound expert testimony, and the related contention that the Federal Rules of Evidence reflect a congressional determination to substitute the adversarial system for the courts' historic responsibility to determine whether a particular expert may testify at all. Part III explains why petitioners' attempted comparison between the use of scientific evidence in the administrative context and in the courts is flawed. Finally, Part IV explains that the courts below correctly excluded petitioners' proffered "scientific" testimony because under the Federal Rules of Evidence, such testimony must be developed according to the scientific method.

ARGUMENT

I. OUR JUDICIAL SYSTEM VESTS SUBSTANTIAL RESPONSIBILITY IN THE COURTS TO CIRCUMSCRIBE EXPERT TESTIMONY

Petitioners have brought this case claiming that the Federal Rules of Evidence were enacted to "limit judicial creativity" (Petitioners' Brief at 25), and to leave courts with little or no authority to fashion or apply guidelines as may be necessary to circumscribe expert testimony. As shown below, petitioners' vision of a neutered judiciary, forced to indulge most any expert testimony, ignores the wide latitude historically afforded experts in our judicial system. The vast scope of this latitude is shown in Part A below. This latitude has in turn fostered checks or "gateways" which logically and historically have been found necessary to limit such testimony. Part B shows that these limits are embodied in the Federal Rules of Evidence.

A. Experts Are Afforded Testimonial Latitude Well Beyond That Afforded Lay Witnesses

Petitioners' analysis initially fails to take account of the extraordinary latitude afforded experts in our scheme of justice. In critical respects, experts, despite their central role in modern litigation, are freed from the substantial constraints imposed on their lay counterparts.

1. *Experts are Free to Render Opinions Not Based on Firsthand Knowledge.* The rule that experts are free to render opinions based on other than firsthand knowledge has long distinguished expert from lay testimony. One of the earliest rules of exclusion at common law held that

witnesses could only testify as to matters within their personal knowledge.[2] An early scholar summarized the state of the law on this point:

> A witness examined as to facts ought to state those only of which he has had personal knowledge . . . . It has been said that a witness must not be examined in chief as to his *belief* or *persuasion*, but only as to his knowledge of the fact . . . . As far as regards mere belief or persuasion which does not rest upon a sufficient and legal foundation, this position is correct,—as where a man believes a fact to be true merely because he has heard it said to be so.

Thomas Starkie, *Evidence* 173 (1824). In essence, then, the so-called "opinion rule" originated as a rule that precluded witnesses from testifying about matters about which they had no knowledge or personal acquaintance. It was, in effect, a "gateway" that precluded certain individuals from testifying at all, or, in Wigmore's words, "merely a recognition of an otherwise established general principle of testimonial qualifications that the witness, to be competent at all, must have personal observation. Had the matter gone no farther, there would have been no separate 'opinion rule,' but merely a special application of an ordinary principle of testimonial competency." 7 John H. Wigmore, *Evidence in Trials at Common Law* § 1917, at 3 (Chadbourn rev. 1978) (citations omitted).

This principle finds full expression in Rule 702 of the Federal Rules of Evidence, which permits an expert to "testify . . . in the form of an opinion or otherwise," and in Rule 703, which permits experts to testify based on information which is simply "made known" to the expert "at or before the hearing." By contrast, Rule 701 continues to require that the opinion of a lay witness be "based on the perception of the witness" and be "helpful to a clear understanding of the witness' testimony."

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[2] This was also a general rule of civil and canon law. *See* William S. Holdsworth, 9 *A History of English Law* 211 n.4 (1926).

2. *Experts Can Testify About Otherwise Inadmissible Hearsay.* The evidentiary rule most frequently associated with the Anglo-American system is the ban on most forms of hearsay testimony.[3] The modern rule, as embodied in Rule 802, is premised on the notion that such evidence is inherently untrustworthy, in large part because it is not amenable to cross-examination.

In salient respects, however, this rule does *not* apply to experts. For instance, Federal Rule 803(18) permits experts to testify about statements contained in published works that are established to be reliable authorities. And Rule 703 permits an expert to base an opinion on facts or data that may otherwise be inadmissible if they are of a type reasonably relied upon by experts in the particular field.

3. *Experts Can Respond to Hypothetical Questions.* At common law and under the Federal Rules, only experts are permitted to respond to hypothetical questions. 2 Wigmore, *supra*, § 679. Prior to enactment of the Federal Rules, however, some courts had required that a hypothetical question (1) include all relevant facts, (2) omit any facts that were not supported or not likely to be supported by evidence before the trier of fact, and (3) be stated in open court. Charles T. McCormick, *McCormick on Evidence* § 14, at 37-38 (Edward W. Cleary *et al.* eds., 3d ed. 1984); 32 C.J.S. *Evidence* § 552 (1964). The Federal Rules liberalized the restrictions on hypothetical questions which may be asked of an expert. The combination of Rules 702, 703 and 705 enables counsel to ask hypothetical questions that incorporate facts or

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[3] Even before there was a generalized rule excluding hearsay, such evidence was viewed as inferior. The push toward adoption of a rule excluding hearsay came in part from a number of celebrated trials during the early sixteenth century in which obvious injustice was wrought by reliance on hearsay. *See generally* Richard O. Lempert & Stephen A. Saltzburg, *A Modern Approach to Evidence* (2d ed. 1983).

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data not actually in evidence, and which need not be disclosed during examination; they can be given to the expert in the secrecy of the office of the counsel who will present him.

4. *Experts Can Testify About Ultimate Issues.* Both the power, and potential danger, of expert testimony lie in large part in the expert's authority to draw conclusions concerning ultimate issues to be decided by the jury. The fact that such testimony arguably invades the province of the factfinder once led many states to exclude such expert opinions in their state court systems. *McCormick on Evidence, supra,* § 12, at 30. The Federal Rules, by contrast, expressly allow testimony on ultimate issues, save in criminal actions where defendant's mental state is an ultimate issue. *See* Fed. R. Evid. 704.[4]

As shown by these examples—of which there are others[5]—many of the fundamental rules of exclusion that promote the reliability of evidence simply do not pertain to experts, notwithstanding that their status in litigation commonly makes experts "as often skillful and effective in producing obscurity and error, as in the elucidation of truth." *McCormick v. Talcott,* 61 U.S. (20 How.) 402, 409 (1857) (Daniels, J., dissenting).

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[4] Federal Rule 704 applies to lay opinions as well as expert opinions. However, lay opinions are governed by the constraint set forth in Rule 701, requiring personal knowledge, and therefore are less likely to be admitted than expert opinions on the ultimate issue.

[5] For instance, experts also are not required to disclose during direct examination the facts or data underlying their opinions (Fed. R. Evid. 705), and can testify about matters that they learn from other witnesses during trial (Fed. R. Evid. 703).

B. The Federal Rules Of Evidence Reimpose Certain Historic Gateways As Necessary Checks On Expert Testimony

Given the extraordinary latitude traditionally afforded expert witnesses, courts and commentators have long recognized the need to impose "gateways" through which expert testimony must pass for it to be considered useful, and ultimately admissible, at trial. At the same time, it has never been thought that any single mechanism could be counted on to rein in expert evidence and curb unsound expert practices. Rather, courts have relied on the fashioning of appropriate principles governing the proper use of expert testimony, coupled with the trial court's exercise of its historic discretion to control the conduct of trials and to see to the proper and fair administration of justice. The so-called *Frye* test is a natural outgrowth of this legacy. *See* Paul Giannelli, *The Admissibility of Novel Scientific Evidence:* Frye v. United States, *A Half Century Later,* 80 Colum. L. Rev. 1197 (1980).

Far from renouncing this legacy—as petitioners suggest—the Federal Rules of Evidence support and reaffirm it. At the heart of the Federal Rules lies the proposition that the federal courts have both the authority and responsibility to employ rules of exclusion and evidentiary limitations to promote the reliability of testimony, whether lay or expert, all to "the end that the truth may be ascertained and [the] proceedings justly determined." Fed R. Evid. 102. The Federal Rules thus outline a series of "gateways" through which proper expert testimony must pass, and which together are intended to assist courts in distinguishing the useful from the useless, the meaningful from the misleading, and the probative from the prejudicial expert testimony.

In particular, the gateways embodied in Rule 702 (permitting scientific testimony only if it is based on "scientific . . . knowledge [that] will assist the trier of

fact"), Rule 703 (requiring that the underpinnings of an expert's opinion be "of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject"), Rule 704 (requiring that opinions on the ultimate issue be "otherwise admissible"), and Rule 403 (excluding relevant testimony if it will, among other things, mislead the jury) provide a flexible yet cohesive scheme for "filtering out" expert opinions which are not firmly rooted in appropriate methodology —which, in the case of scientific testimony, means opinions not rooted in the scientific method. Simply stated, an expert's opinion on an issue of science which is developed without regard to the scientific method cannot constitute "scientific" knowledge within the meaning of Rule 702, and therefore can only "mislead[]," "confus[e]," and "prejudice" the factfinder as those terms are used in Rule 403. Evidence which appears to be scientifically objective, but which in reality is not, cannot "assist the trier of fact" as Rule 702 requires. The Ninth Circuit properly applied such constraints on expert testimony in excluding petitioners' scientific testimony.

II. THE FEDERAL RULES OF EVIDENCE NEITHER REQUIRE NOR PERMIT COURTS TO ABDICATE THEIR HISTORIC RESPONSIBILITY TO CIRCUMSCRIBE EXPERT TESTIMONY

Petitioners suggest that the Federal Rules of Evidence reflect a determination by Congress to "let it all in"—that is, to impose few if any constraints on the admissibility of expert testimony in the first instance, and to rely on the adversarial system for weeding out unsound scientific testimony and methodology. Petitioners' Brief at 15, 39-40. This view reflects not only a misreading of the terms and spirit of the Federal Rules, but a naive assessment of the potency of unsound scientific evidence in the courtroom.

A. Cross-Examination Is Not A Meaningful Substitute For Judicial Scrutiny

Few would deny that in many situations, cross-examination is an effective constraint on aberrant testimony. Effective cross-examination, however, presupposes that the jury will be able to understand the testimony and thus appreciate the weaknesses made evident during cross-examination.[6] There is no such presupposition in the context of expert testimony. To the contrary, the very reason for permitting expert testimony in the first place suggests that lay factfinders may not be able to fully comprehend and evaluate the testimony before them. This inability to fully appreciate scientific evidence can arise even in relatively straightforward cases, and can often lead a factfinder to embrace the fallacy that because one development follows another, the two are causally related.[7]

Concern over the ability of lay factfinders to fully comprehend complex expert evidence is not new. Learned Hand astutely highlighted the conundrum when he wrote:

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[6] Effective cross-examination also presupposes that attorneys will have ample opportunity to take discovery sufficient to conduct effective cross-examination. Yet federal discovery rules substantially restrict the opportunities and methods for discovering experts. Furthermore, recent amendments to the Federal Rules of Civil Procedure curtail the ability of parties to fully discover each other's experts. *See* Paul F. Rothstein, *The Collision Between New Discovery Amendments and Expert Testimony Rules*, Litigation, Spring 1988, at 17. And, of course, in criminal cases there is virtually no discovery.

[7] With such *post hoc* reasoning, one concludes that because event A preceded event B, it must have caused event B. For example, we may see an eclipse of the sun. We then beat on a drum. The eclipse disappears and the sun is restored. We conclude that beating the drum caused the sun to reappear. Alvan R. Feinstein, *Clinical Epidemiology: The Architecture of Clinical Research* 41-42 (1985). Scientific research is designed to avoid the *post hoc* fallacy.

> The whole object of the expert is to tell the jury, not facts, as we have seen, but general truths derived from his specialized experience. But how can the jury judge between two statements each founded upon an experience confessedly foreign in kind to their own? It is just because they are incompetent for such a task that the expert is necessary at all.

Learned Hand, *Historical and Practical Considerations Regarding Expert Testimony*, 15 Harv. L. Rev. 40, 54 (1902). This concern is all the more warranted as science-driven disputes increasingly wend their way through the federal courts. The burden on jurors is especially acute where, as here, they are asked to determine causation based on a reanalysis of epidemiological data culled *ad hoc* from a variety of previously published studies all of which point in the direction of no causation.[8]

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[8] In a sobering study, Dr. Molly Treadway Johnson, now of the Federal Judicial Center, sought to determine experimentally the ability of lay jurors to comprehend epidemiological evidence bearing on causation. Molly Treadway, *An Investigation of Juror Comprehension of Statistical Proof of Causation* (1990) (unpublished Ph.D. dissertation, Johns Hopkins University). In one experiment, 25 jurors who had been called for jury duty in Baltimore state court were shown two sets of epidemiological data and were asked to answer four questions about those data (*e.g.*, whether the results of the study indicate that being exposed to a given substance increases a person's risk of developing a certain abnormality). Out of 100 yes-no responses, only 41 were correct and only two subjects (or eight percent) answered all four questions correctly. In short, subjects performed worse than chance. In a second experiment, Dr. Johnson exposed one group of 30 jurors to a videotaped, simulated deposition in which an epidemiologist was being questioned by a lawyer. The tape was designed to teach the jurors how to use epidemiological information. A second group of 15 jurors was not shown the tape. Overall, only three subjects answered all four questions correctly. Dr. Johnson found that "there was no difference . . . between the expert and no-expert groups in terms of the number of subjects who used a correct approach at least once." *Id.* at 82-83. "It appears, then, that the expert testimony did not provide subjects with an understanding of how to analyze and interpret epidemiological data." *Id.* at 83. She concluded that

> [t]he results of Experiments 1 and 2 paint a rather dismal picture of lay jurors' abilities to understand epidemiological analysis. Subjects began with a poor understanding of epidemiological reasoning, and apparently were not helped when provided with expert testimony. Thus, the initial question of whether lay jurors are generally capable of understanding statistical proof of causation as it is presented under the current system must be answered in the negative.

Id. at 88.

Beyond the jury's lack of competence in many circumstances to evaluate the success of cross-examination, the very mystique of science is such that its admission alone may prejudice the opponent's opportunity for a fair trial beyond the curative powers of cross-examination. Even staunch advocates of the "let it all in" approach, such as Professor Tribe, acknowledge that

> the very mystery that surrounds mathematical arguments—the relative obscurity that makes them at once impenetrable by the layman and impressive to him—creates a continuing risk that he will give such arguments a credence they may not deserve and a weight they cannot logically claim.

Laurence H. Tribe, *Trial by Mathematics: Precision and Ritual in the Legal Process*, 84 Harv. L. Rev. 1329, 1334 (1971).[9] This is only to acknowledge that scientific studies have an inherent aura about them which, if not properly checked, can "assume a posture of mystic infallibility in the eyes of a jury of laymen," *United States v. Addison*, 498 F.2d 741, 744 (D.C. Cir. 1974),

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[9] Professor Tribe was writing in part about *People v. Collins*, 438 P.2d 33, 33 (Cal. 1968), where the California Supreme Court, in reversing a conviction based on the erroneous mathematical reasoning of an expert witness, warned that "[m]athematics, a veritable sorcerer in our computerized society, while assisting the trier of fact in the search for truth, must not cast a spell over him."

with the result that jury decisions may clash with "generally accepted scientific understandings." Note, *A Question of Competence: The Judicial Role in the Regulation of Pharmaceuticals*, 103 Harv. L. Rev. 773, 780 (1990).

Furthermore, the rigid "let it all in" philosophy espoused by petitioners would impose enormous costs on society, on parties to litigation, and on our system of justice. When no or unduly low standards on expert participation are imposed in the first instance, the testimony that results will often be of little or no evidentiary value, yet may still consume vast amounts of the courts' and the parties' resources. *See Winans v. New York & Erie R.R. Co.*, 62 U.S. (21 How.) 88, 101 (1858). Moreover, excessive leniency in permitting the introduction into court of "science," however dubious its methodology, leads companies to question the wisdom of carrying on with the development of novel products which may invite courtroom attack.

If jurors have difficulty understanding epidemiological and other scientific evidence, it is unrealistic to presume that cross-examination, no matter how skillfully conducted, can remedy the use of unsound expert evidence. In such a setting, the imposition of reasonable gateways is imperative.

B. The Federal Rules of Evidence Neither Require Nor Countenance Slavish Reliance On The Adversarial System To Weed Out Unsound Expert Testimony

The position embraced by petitioners not only overstates the efficacy of the adversarial system in weeding out unsound expert evidence, but reflects a misreading of the Federal Rules. In particular, this view is in error because it reads the Rules piecemeal and out of context, rather than as a matrix of interdependent rules of exclusion. The Advisory Committee notes make clear that Congress envisioned that the courts would apply the

Rules not in isolation but as a cohesive code. Thus, in introducing Rule 704 permitting opinion testimony on ultimate issues, the Committee noted:

> The abolition of the ultimate issue rule does not lower the bars so as to admit all opinions. Under Rules 701 and 702, opinions must be helpful to the trier of fact, and Rule 403 provides for exclusion of evidence which wastes time. These provisions afford ample assurances against the admission of opinions which would merely tell the jury what result to reach . . . . They also stand ready to exclude opinions phrased in terms of inadequately explored legal criteria.

In practice, federal courts have applied the Federal Rules of Evidence as a *code*, mindful of its conceptual unity.[10]

The "let it all in" approach also overlooks the express mandate that the Rules be construed so as to "secure fairness in administration" and "elimination of unjustifiable expense and delay." Fed. R. Evid. 102. As noted above, unjustified expense and delay would be the predictable result were the Federal Rules construed, as petitioners suggest, to eliminate the authority of trial courts to apply rules of exclusion so as to filter out "misleading" evidence of no "assist[ance]" to the trier of fact.

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[10] *See, e.g., United States v. Schatzle*, 901 F.2d 252, 257 (2d Cir. 1990) ("[a]lthough the Federal Rules of Evidence do not bar all expert testimony concerning an ultimate issue . . . a district court may exclude ultimate issue testimony under Federal Rule of Evidence 702 when it is not helpful to the jury, or under Rule 403 when it may be unduly prejudicial"); *United States v. Scavo*, 593 F.2d 837, 844 (8th Cir. 1979); *United States v. Brown*, 776 F.2d 397, 401 (2d Cir. 1985), *cert. denied*, 475 U.S. 1141 (1986) (though expert testimony was not barred by Rule 704(b), "district judges should heed the Advisory Committee's Note to Rule 704" and also consider other "precautionary observations about the admission of [expert] testimony").

III. PETITIONERS' ANALOGY TO THE USE OF SCIENTIFIC EVIDENCE BY ADMINISTRATIVE AGENCIES IS UNTENABLE

Petitioners and certain *amici* challenge the conclusion of the Ninth Circuit because various federal agencies are willing to take regulatory action based on unpublished scientific research or in the absence of positive epidemiological studies. *See, e.g.*, Petitioners' Brief at 12 n.39; Brief of *Amici Curiae* of Physicians, Scientists and Historians of Science in Support of Petitioners at 18; Brief of *Amici Curiae* American Society of Law, Medicine and Ethics *et al.* at 10. In fact, the actions of federal regulatory agencies are not germane to the issues raised in this case for several reasons.

First, if procedures used by those agencies to assess risks were applied here, petitioners' claims would vanish. Simply stated, the United States Food and Drug Administration, the premier agency in assessing the safety and efficacy of drugs, has already determined that Bendectin is "safe" and "effective." *See* Federal Food, Drug, and Cosmetic Act § 505(b), 21 U.S.C. § 355(b) (1988) (setting forth prerequisites for FDA approval).

Moreover, petitioners overlook the differences between administrative "risk assessment" and judicial factfinding. Administrative action is aimed at regulating *future* conduct. *See, e.g., Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988). The statutory missions of federal agencies include apprising the public of perceived future risks and setting standards to reduce such risks. For example, the National Toxicology Program lists a substance in the Annual Report on Carcinogens if that substance is "reasonably . . . anticipated to be [a] carcinogen[]." Public Health Service Act § 301(b)(4), 42 U.S.C. § 241(b)(4) (1988). The purpose of the Annual Report is risk identification, not resource reallocation.[11] However, the Program's listing does not penalize a manufacturer for *past* conduct. Regulatory action can be triggered even in the absence of an established cause-and-effect relationship. In sharp contrast, tort litigation judges past conduct, and shifts resources only where that past conduct *actually caused* the plaintiff's injuries.

In addition, the gateways so essential to the trial process for ensuring reasoned and consistent decision-making are not nearly as critical in the regulatory process. Unlike jurors, those making regulatory decisions often deal with scientific issues as part of their job, and are able to fully evaluate such evidence and ascertain potential risks. Moreover, since the decisions reached by agencies govern entire enterprises or lines of commerce, consistency is better assured. And finally, administrative agencies are expressly authorized to consider evidence that would ordinarily not be admissible in a court of law. *See* Administrative Procedure Act, 5 U.S.C. § 556(d) (1988) ("[a]ny oral or documentary evidence may be received" in administrative proceedings); *Richardson v. Perales*, 402 U.S. 389, 409 (1971); *McCormick on Evidence, supra*, § 352, at 1009 ("[a]dministrative agencies generally are not restricted in the kind of evidence they can admit").

In short, while one can draw meaningful lessons from the actions of administrative agencies that might be of

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[11] As such, a substance will be listed by the National Toxicology Program in the Annual Report even though there is no evidence of a cause-and-effect relationship between it and cancer; a mere association in animal studies will in the agency's view suffice. *See* Public Health Service, U.S. Dept. H.H.S., *Sixth Annual Report on Carcinogens* viii (1991). It bears noting that in spite of the Program's low threshold, "[o]nly substances for which the evidence of carcinogenicity has been peer-reviewed are evaluated for possible inclusion in the Annual Reports." *Id.* There is doubt, even within the agency, that this low threshold is consistent with the Program's statutory mandate. *See generally* Final Report of the Advisory Review by the National Toxicology Program Board of Scientific Counselors, 57 Fed. Reg. 31,721 (1992).

some use in the context of private litigation, the analogy pressed by petitioners goes too far. Administrative action is prophylactic and not retrospective; its purpose is to warn of possible health effects and not to judge whether a given agent in fact caused a specified ailment. Administrative action in the health sciences is undertaken by trained professionals pursuant to a statutory mandate, not by jurists and jurors. And administrative agencies, unlike federal courts, are not bound by the Federal Rules of Evidence.

What petitioners ultimately fail to acknowledge, then, is that legal systems fulfill a number of salutary purposes. They provide a socially acceptable means of resolving disputes, and lend a degree of certainty essential if people and enterprises are to invest in ideas and products. Fostering certainty, a fundamental goal of the Anglo-American system, is possible only where the rules that guide judicial decision-makers comport with those that guide responsible decision-makers in the private sector. Products developed through experimentation according to the rigors of the scientific method can be fairly judged only in light of that same method.

Petitioners' attempt to equate administrative and judicial action also obscures the fact that to condone tort liability based on opinions developed without regard to the scientific method increases uncertainty and, correspondingly, poses a significant disincentive to the development of new products. *See* Mahoney & Littlejohn, *Innovation on Trial: Punitive Damages Versus New Products*, 246 Science 1395, 1397 (1989) ("inhibiting effect of expanded product liability may permeate a firm's entire decision-making process"). This problem is particularly acute in the health care sector, where drug manufacturers

> might be reluctant to undertake research programs to develop some pharmaceuticals that would prove beneficial or to distribute others that are available to

> be marketed, because of the fear of large adverse monetary judgments. Further, the additional expense of insuring against such liability—assuming insurance would be available—and of research programs to reveal possible dangers not detectable by available scientific methods could place the cost of medication beyond the reach of those who need it most.

Brown v. Superior Court (Abbott Laboratories), 751 P.2d 470, 479 (Cal. 1988) (highlighting examples in which drugs and vaccines were withdrawn or not introduced because of liability concerns). In this regard, too, it is important to distinguish evidentiary rules that exclude aberrant testimony when judging past conduct from those rules used by administrative agencies in regulating future conduct.

IV. SCIENTIFIC EXPERT TESTIMONY MUST BE DEVELOPED IN ACCORD WITH THE SCIENTIFIC METHOD

This case shows the perils of unchecked expert testimony in the context of complex scientific evidence. For instance, the dangers inherent in permitting experts to offer opinions on ultimate issues were exemplified by the expert affidavits submitted to the district court by petitioners, which are rife with opinions about ultimate issues. Thus, Dr. John Palmer, although having never examined the Daubert or Schulier children or their mothers, nonetheless stated in his affidavit that "it is my opinion . . . that in each case the drug Bendectin was taken at the period of time such as to effect [sic] the cells that would produce the normal limb structure and that Bendectin did cause the limb defects in each of the children." J.A. 192. Such a conclusion, given its "scientific" underpinnings, is "likely to be shrouded with an aura of near infallibility, akin to the ancient oracle of Delphi" (*United States v. Alexander*, 526 F.2d 161, 168

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(8th Cir. 1975)), particularly given the jurors' predictable lack of facility for scientific information.[12]

Likewise, the rule permitting experts to answer hypothetical questions increases the likelihood that jurors will accept as true those "facts" that have been artfully incorporated into the question even though there is no evidentiary basis for accepting their validity.[13] This concern too was borne out in the case below when one of petitioners' experts, Dr. Swan, testified about "Type II errors" and concluded erroneously that there is an association between Bendectin and limb reductions.[14] Petitioners summarized her testimony as follows:

[12] In fact, one study revealed that 70 percent of attorneys and judges surveyed believed that juries accord scientific evidence more credibility than other evidence. Michael J. Saks & Richard Van Duizend, *The Use of Scientific Evidence in Litigation* 5-6 (1983) (citing results of O. Schroeder, *The Forensic Sciences in American Criminal Justice: A Legal Study Concerning the Forensic Sciences Personnel* (Forensic Sciences Foundation n.d.)).

[13] This is of more than hypothetical concern: a substantial body of literature suggests that individuals are influenced by information embedded in questions. In one study, subjects were shown a film of an automobile accident. Some were asked: "How fast was the white sports car going when it passed the barn while traveling along the country road?" No barn existed. Other subjects were asked the control question: "How fast was the white sports car going while traveling along the country road?" Subjects in the first group were significantly more likely to indicate the presence of the non-existent "barn" during follow-up questioning than were subjects in the second group. Elizabeth F. Loftus, *The Malleability of Human Memory*, 67 Am. Scientist 312, 312 (1979). *See* Elizabeth F. Loftus & David G. Miller, *Semantic Integration of Verbal Information into a Visual Memory*, 4 J. Exp. Psychol. 19 (1978); G.R. Potts, *Integrating New and Old Information*, 16 J. Verb. Learning & Verb. Behav. 305 (1977); Elizabeth F. Loftus, *Leading Questions and the Eyewitness Report*, 7 Cognitive Psychol. 560 (1975); Elizabeth F. Loftus & John C. Palmer, *Reconstruction of Automobile Destruction: An Example of the Interaction Between Language and Memory*, 13 J. Verb. Learning & Verb. Behav. 585 (1974).

[14] Epidemiologic studies involve consideration of two statistical possibilities: stating that a relationship exists when in fact it does not (Type I error), and failing to observe a relationship when one actually exists (Type II error). In the Bendectin studies, a Type I error occurs if a researcher erroneously concludes that Bendectin is associated with limb reductions, when in fact no relationship exists. In contrast, a Type II error is committed if the researcher concludes that there is no relationship between the drug and limb reductions when one actually exists.

> Dr. Swan calculated the risk of Type II error from the Bendectin studies and found, as to each study, that *even if Bendectin were causing a doubling of the incidence of human limb reductions* there was less than a 20% chance that the study would yield a "statistically significant" outcome if "significance" was [sic] defined as confidence at the 95% level.

Petitioners' Brief at 9-10 (footnote omitted). What petitioners neglect to note is that in order to calculate the probability of a Type II error one must *assume* an alternate hypothesis. *See* B.J. Winer, *Statistical Principles in Experimental Design* 11-14 (2d ed. 1971); Leonard M. Horowitz, *Elements of Statistics for Psychology and Education* 243-50 (1974). Thus, Dr. Swan *assumed* for purposes of her calculation that Bendectin *doubled* the risk of limb reductions. There is literally no evidence in the record, or anywhere else for that matter, that supports Dr. Swan's alternate hypothesis, *i.e.*, a doubling of the risk. Thus, while her testimony appears on its face to be highly probative, it in fact lacks evidentiary value.[15]

[15] As the Group of American Law Professors noted in their *amicus curiae* brief (at 22), "science subjects theories, hypotheses and common sense to systematic test." Dr. Swan's alternate hypothesis fails that test. If Bendectin in fact increased the risk of limb reductions by a factor of two and if, as a result, the probability of there being a Type II error were 80 percent, then one would expect that of the ten epidemiological studies dealing with limb reductions, eight would show a statistically significant association. In fact, none did. The probability that none would show a statistically significant association, given Dr. Swan's alternate hypothesis, is less than eleven percent. Dr. Swan also appeared to ignore one study in which researchers, after finding no associa-

In these and other respects, the Bendectin litigation shows what can go wrong when courts do not impose sufficient "gateways" governing the introduction of scientific expert testimony. The gateways embodied in the Federal Rules provide a series of threshold tests against which such scientific opinion must be measured. These tests have their roots both in the language of the Federal Rules and in the scientific method. We submit that the tenets of the scientific method articulate what amounts to a minimum universal standard against which all putative scientific opinion should be judged, a common denominator linking the *Frye* test and its various adaptations.

Opinion as to an ultimate fact developed without regard to the scientific method does not qualify as "scientific knowledge" as that term is used in Rule 702. Since it would not be relied upon by scientists in the field, it would not "assist the trier of fact" as required by Rule 702, or be said to be based on data or methodology "reasonably relied upon" by those in the field as required by Rule 703. Furthermore, since an opinion developed without regard to the scientific method appears to have scientific authority that it in fact does not have, it is "misleading" and "prejudic[ial]" within the meaning of Rule 403. This does not mean that novel scientific findings that diverge from accepted notions ought to be rejected. The scientific method does not denigrate novel results even where they may clash with commonly held beliefs. The scientific method speaks to the *process* by which the scientist reached a conclusion, not to the conclusion itself, thereby ensuring the orderly growth of knowledge. As such, the scientific method and the philosophy underlying the Federal Rules are both premised

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tion between Bendectin and limb reductions, stated that there was only an 18 percent chance of missing a two-fold increased risk to Bendectin-users, *i.e.*, the probability of a Type II error for the study was 18 percent. S. Morelock *et al.*, *Bendectin and Fetal Development: A Study at Boston City Hospital*, 142 Am. J. Obstet. & Gynecol. 209, 212 (1982).

ultimately on the same objective: the efficient search for truth. *See* Fed R. Evid. 102.

In particular, the scientific method [16] requires that one (1) first set forth a hypothesis,[17] (2) design an experiment, or more properly a set of experiments, to test the hypothesis,[18] (3) conduct the experiment, collect the data, and then analyze those data, (4) publish the results so that they may not only add to the body of knowledge, but also be subject to external scrutiny,[19] and (5) ensure that those results are replicable and verifiable.[20]

When judged against these standards, petitioners' proffered expert testimony fails to measure up. Petitioners did not negate the hypothesis that there is no association between Bendectin and limb reductions; did not establish any alternate hypothesis in accord with the scientific method; did not publish their work for proper peer review; and otherwise did not adhere to standard scientific methodology. Indeed, petitioners did little more than

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[16] The rudiments of the scientific method derive from the work of Bacon, Galileo and Newton. *See* Ernan McMullin, *The Development of Philosophy of Science 1600-1900*, Companion to the History of Modern Science 816 (R.C. Olby *et al.* eds., 1990). The pioneering work of British statistician Sir Ronald A. Fisher underlies the design of scientific experiments more generally. *See* Ronald A. Fisher, *The Design of Experiments* 11-26 (8th ed. 1966).

[17] *See* Martin Goldstein & Inge F. Goldstein, *How We Know: An Exploration of the Scientific Process* 19 (1978).

[18] *See* Francisco J. Ayala & Bert Black, *The Nature of Science and the Problem of Demarcation*, 1 Science and Courts 1 (forthcoming 1993).

[19] *See generally* John M. Ziman, *Reliable Knowledge: An Exploration of the Grounds for Belief in Science* (1978). *Cf. People v. Collins*, 405 N.Y.S.2d 365, 369 (Sup. Ct. 1978) (new theories must be "tested in the crucible of controlled experimentation and study," a procedure that requires "replication of original experiments, and scrutiny of the results in various scientific journals").

[20] *See* Karl R. Popper, *The Logic of Scientific Discovery* 44-45, 53-54 (rev. ed. 1972).

criticize the work of other scientists. But critiquing another's study does not validate one's own. Yet, under petitioners' conception of a shackled judiciary, such testimony—though it does not qualify as "scientific knowledge" capable of supporting their burden of proof—would nevertheless be presented to the jury.

When attempting to draw scientific conclusions, whether at the laboratory bench or the courtroom bar, one should at a minimum be required to formulate those conclusions in accord with the scientific method. That method provides a straightforward, relatively simple, and reasonable test for the admissibility of expert opinion. It is a test, moreover, which federal judges can readily apply, and which, in cases like this, would enable them to unearth the fallacies in unsound scientific evidence. It does not require the court to make value judgments about the legitimacy of the results, or to reject novel scientific conclusions merely because they are novel. Rather, it provides the court with guidance for measuring proffered evidence against a time-honored threshold, a threshold which simultaneously promotes novelty and reliability.

In sum, *amici* submit that the gateways reaffirmed by the Federal Rules of Evidence in effect incorporate the scientific method, and that the *Frye* test represents one appropriate way of adapting the scientific method to the courtroom setting.

CONCLUSION

Petitioners' expert testimony was properly excluded. The judgment below should be affirmed.

Respectfully submitted,

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